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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,900	12/02/2003	J. Glenn Morris	62610.000035	2442

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EXAMINER	
JOIKE, MICHELE K	

ART UNIT	PAPER NUMBER
1636	

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05/14/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,900	MORRIS ET AL.	
	Examiner	Art Unit	
	MICHELE K. JOIKE	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5-21,29-32 and 34-52* is/are pending in the application.

4a) Of the above claim(s) *18-21,51 and 52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 5-17, 29-32, 34-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed February 15, 2008. Claims 1, 3, 5-21 and 29-32, 34-52 are pending in the instant application. Claims 1, 3, 5-17, 29-32 and 34-50 are examined. Any rejection of record in the previous Office Action, mailed October 16, 2007 that is not addressed in this action has been withdrawn.

Because this Office Action introduces new rejections other than those set forth in the previous Office Action, and are not necessitated by amendment, this Office Action is **Non-Final**.

Election/Restrictions

Applicants are arguing the withdrawal of claims 51 and 52. The argument is that the step of providing bacteriophage to a colonized patient "wherein the bacteria have already colonized the patient" is required in the amended claims and in claim 51. The Examiner disagrees and still maintains that the elected invention is drawn to a method of reducing the risk of bacterial infection, wherein bacteria have already colonized the patient, while claims 51 and 52 are drawn to a method of reducing the risk that persons who have not been colonized will acquire pathogenic bacteria. The patients are at different stages.

Response to Arguments Concerning Claim Rejections – *35 USC § 102 (b)*

Applicants' arguments filed on February 15, 2008 have been fully considered. The following grounds of traversal are presented:

US 6,056,954 only teach the use of lytic enzymes to treat bacterial infections, and does not teach a method comprising treating a patient with a composition comprising bacteriophage.

Applicant's traversal has been fully considered and found to be persuasive in that US 6,056,954 does not teach a method comprising treating a patient with a composition comprising bacteriophage. However, new grounds of rejection under 35 U.S.C. 103(a) recited below.

Response to Arguments Concerning Claim Rejections – *35 USC § 103 (a)*

Applicants' arguments filed on February 15, 2008 have been fully considered. The following grounds of traversal are presented:

US 6,056,954 only teach the use of lytic enzymes to treat bacterial infections, and does not teach a method comprising treating a patient with a composition comprising bacteriophage. Neither Carlton nor Risi cure the deficiencies.

Applicant's traversal has been fully considered and found to be persuasive in that US 6,056,954 does not teach a method comprising treating a patient with a composition comprising bacteriophage, and neither Carlton nor Risi cure this particular deficiency. However, Carlton and Risi are used in new grounds of rejection under 35 U.S.C. 103(a) recited below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 7-9, 32, 35, 37-39 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,056,954 in view of US 2005/0260171.

Applicants claim a method for reducing the risk of bacterial infection or reducing the level of colonization in a patient by treating the patient with a bacteriophage composition before the patient develops an illness. The treatment reduces the level of colonization by at least one log. The patient is colonized with the pathogenic bacteria, which is from *Hemophilus* or is *Escherichia coli*. The bacteriophage composition can be an oral tablet, liquid, nasal aerosol, throat

wash, toothpaste or topical ointment. The topical ointment can be used to treat a wound.

US 6,056,954 (specifically columns 2, 3 and 5) teaches a method of using lytic enzymes for preventing those who have been exposed to others who are sick, from becoming infected. As noted by Applicants, the reference is teaching the use of lytic enzymes instead of bacteriophages. However, introducing bacteriopahges will cause production of lytic enzymes. As stated in claim 1, introducing a bacteriophage will "produce lytic infections in said pathogenic bacteria". Therefore, it would be obvious to one of skill in the art to use the entire bacteriophage instead of the lytic enzymes, because it would have achieved the predictable result of lysing the bacteria. The patient is colonized with the pathogenic bacteria, which is from *Hemophilus* or is *Escherichia coli*.

The bacteriophage composition can be an oral tablet, liquid, nasal aerosol, throat wash, toothpaste or topical ointment. The topical ointment can be used to treat a wound. Applicant does not define "deep penetrating wound", so the Examiner is interpreting the burns and wounds discussed in column 3 to be deep penetrating wounds.

Although US 6,056,954 does not teach reducing the level of colonization of the bacteria by at least one log, US 2005/0260171 (specifically Ex. 9) teaches the application of a bacteriophage preparation to *S. aureus* isolates. Out of nine different samples of *S. aureus,* the bacteriophage was effective in killing five of the nine. By killing 5 of the 9 isolates, the colonization was reduced by at least one log. It would have been obvious to one of ordinary skill in the art to kill the

bacteria to yield the predictable result of reducing colonization of the bacteria, because it necessarily follows that killing the bacteria reduces the number of bacteria present, a person of skill in the art would know that killing bacteria is an effective way to reduce colonization.

Claims 3, 6, 10-16, 17, 29-31, 34, 36 and 40-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,056,954 as applied to claims 1, 4, 5, 7-9, 32, 35, 37-39 and 48-50 above, and in view of Carlton, R. and in further view of Risi et al.

Applicant further teaches that the patient is immunocompromised. The pathogenic bacteria are VRE or MDRSA or multi-drug resistant *Pseudomonas*. The composition can contain a plurality of bacteriophage strains to produce lytic infections against a plurality of bacterial species. The method can also be used to reduce the incidence of bacterial infections of patients admitted to a hospital.

US 6,056,954 and US 2005/0260171 teach all of the limitations as described above. However, they do not teach that the patient is immunocompromised, the pathogenic bacteria are VRE or MDRSA or multi-drug resistant *Pseudomonas*, the composition can contain a plurality of bacteriophage strains to produce lytic infections against a plurality of bacterial species, or that the method can also be used to reduce the incidence of bacterial infections of patients admitted to a hospital.

Carlton (Archivum Immunologiae et Therapiae Experimentalis 47: 267-274, 1999, specifically pp. 267, 268 and 272) teaches using phage therapy to

treat bacterial infections. The pathogenic bacteria treated can be VRE. The composition can contain a grouping of phages to attack more than one bacterial species. Carlton also discloses that hospitals routinely apply a topical phage ointment on surgical incisions to prevent infection. However, Carlton does not teach phage therapy for immunocompromised patients, or treating MDRSA or multi-drug resistant *Pseudomonas.*

Risi et al (Am J Infect Control 26: 594-606, 1998, specifically pp. 594, 596, 601) teaches prevention of infection in the immunocompromised patient. The immunocompromised patient could have cystic fibrosis or AIDS (see Box 2 and p. 596). It is also understood that more than one patient can be treated. The bacterial infections could be VRE, MDRSA or multi-drug resistant *Pseudomonas.*

The ordinary skilled artisan, desiring to reduce the risk of bacterial infection or reduce the level of colonization in a patient by treating the patient with a bacteriophage composition before the patient develops an illness, would have been motivated to combine the teachings of US 6,056,954 teaching a method of using lytic bacteriophages for preventing those who have been exposed to others who are sick, from becoming infected by pathogenic *Hemophilus* or *Escherichia coli*, by administering a bacteriophage composition as an oral tablet, liquid, nasal aerosol, throat wash, toothpaste or topical ointment, with the teachings of Carlton teaching using phage therapy to treat VRE infections, with Risi et al teaching prevention of infection in the immunocompromised patient, having cystic fibrosis or AIDS because treating a bacterial infection, such as a VRE infection, with bacteriophage is advantageous

because Carlton teaches that one phage particle is sufficient to kill a given bacterium and phages are living organisms that can undergo mutations, some of which can overcome bacterial mutations. It would have been obvious to one of ordinary skill in the art to treat an immunocompromised patient with AIDS or cystic fibrosis who has a VRE, MDRSA or drug-resistant *Pseudomonas* because Risi et al teach that infectious diseases represent a major cause of morbidity and mortality in immunocompromised patients. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.
Examiner
Art Unit 1636

/David Guzo/
Primary Examiner
Art Unit 1636